The following e-mail was sent today to Mindy Littell of the Wireless Telecommunications Bureau on behalf of the Hearing Industries Assn.:

This will respond to your request for a citation to a legal requirement as to the level at which claims on a label on a hearing aid must be satisfied to avoid FDA sanctions.

The requirement is not expressed in a specific regulation. When any claim is made about a medical device, studies supporting the claim must be undertaken, and the results must be retained by the manufacturer and produced if ordered by the FDA. Very little leeway is permitted for failure to meet claims for medical devices, because of the potentially serious consequences to health if an individual unit of any medical device does not meet a claim.

The FDA material that Carole Rogin sent you includes criteria for making claims:

"few" means 0-25%
"some" means 26-50%
"many" means 51-75%
"most" means 76-100%

Under these criteria, if fewer than 100% of units of a particular model hearing aid were compatible with all cellphones, then a claim of compatibility could at best be made only for "most" units. The Hearing Industries Association believes that a label on hearing aids claiming that "most" are compatible with "most" or "many" or "some" cellphones would be essentially meaningless to hearing impaired consumers, because each consumer buys only one hearing aid or pair of aids. An individual consumer is not interested in statistics; he or she wants to know whether the specific unit(s) he or she bought will work.

Because handsets are not subject to FDA regulations, the handset industry is not subject to similar sanctions if they claim that a handset complies with the ANSI standard, or perhaps that it "is designed to comply" with the standard. The hearing aid industry has undertaken the responsibility of finding a hearing aid for each consumer that will work with a compliant handset. The promise is not that any specific aid will work but that the dispenser will find some aid that works for each consumer, even if it is a different model from the consumer's initial selection.

If a hearing aid dispenser were unable to find any hearing aid that worked with an individual handset unit, a question might arise as to whether that handset unit complied with its claim to meet the ANSI standard. Cellular telephones are so commonplace today that a dispenser would have no difficulty finding two or three other handsets with which to test a hearing aid. If the aid worked with all handsets other than the one purchased by the hearing impaired customer, a question would arise as to whether that particular handset were defective or non-compliant. In that situation, the only risk on the part of the handset provider would be the need to make an exchange under a warranty or trial return policy; there would be no suggestion of the sanction of revocation of the FCC equipment authorization unless the violation were willful or

repeated or the result of poor design or manufacturing controls rather than inadvertence. On the other hand, if the hearing aid worked with none of the handsets that claimed to be compliant, the dispenser would go back to the drawing board to reconfigure or replace the aid.

I hope this answers your question. HIA would be happy to meet again to discuss this issue if it would be helpful to you or anyone at the Commission.

I plan to send a copy of this e-mail to the docket file via ECFS.

Peter Tannenwald